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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,324	01/24/2000	Knappik Achim	047744/0106	7002

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EXAMINER	
CLOW, LORI A	
ART UNIT	PAPER NUMBER
1631	16

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/490,324	ACHIM ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/025769

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 56-61 are currently pending in the application.

Priority to PCT/EP/03647 filed 19 August 1996 and EP 95113021 filed 8 August 1995 is acknowledged.

Claim Rejections - 35 USC § 112

Claims 56, 57 and 59-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite "a collection of (poly)peptides" in reference to claim 56. However, claim 56 states only a single (poly)peptides, not a collection. Further, claim 56 also recites an amino acid sequence "capable of being identified". It is unclear as to what is meant by "capable of". Does the amino acid sequence have a particular domain that is readily recognized and that is universal to all amino acids?

In claim 56, step (a), how many amino acids are necessary to define a consensus sequence?

In step (b), how are amino acids to be modified actually identified? What basis constitutes whether or not an amino acid has to be modified?

In step (c) which (poly)peptide sub-element is being identified? The (poly)peptide from (a) or (b) or both?

In step (e), what constitutes "setting up" cleavage sites? Are these sites incorporated into the sequences?

In claims 58 and 59, the mere recitation of a "kit" fails to distinguish the claims over claim 56. The addition of a container, carrier, diluent etc, (for example) to the claim language would clarify the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 56-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al. (US Patent 5,693,493).

The instant claims are drawn to polypeptide sequences comprising amino acid consensus sequences capable of being identified by various steps that include deducing homologous proteins, identifying modifiable amino acids, identifying sub-elements, and setting up cleavage sites.

Robinson et al. disclose consensus sequences of light and heavy chain J regions of the immunoglobulin genes useful in the design of oligonucleotides for use as primers or probes for cloning Ig light or heavy chain mRNAs or genes (column 12, lines 57-62). Each domain in the immunoglobulin genes is arranged in modules and flanked by unique restriction sites (see figures 7 and 12;column 27 lines 40-55; examples). A variety of CDR sequences (for various antigens) can thus be cloned into a framework sequence to provide a polynucleotide sequence that encodes an Ig with a particular binding specificity (column 34, line 23-column 35, line 63). These sequences can further be cloned into appropriate vectors for expression in eukaryotic or prokaryotic host cells to express the encoded polypeptides. Kits comprising these sequences are contemplated, for instance, in the identification of pectate lyase genes.

Claims 56-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Queen et al. (US 5,693,761).

Queen et al. disclose methods of preparing polynucleotides comprising humanized Ig sequences, which include one or more CDR regions and four framework regions. A variety of CDRs can be cloned into the humanized framework (see abstract). The preferred methods include first comparing the framework or variable region amino acid sequence of the donor Ig to corresponding sequences in a collection of human Ig chains and then selecting as the human Ig one or more homologous sequences from the collection (column 2, lines 41-46). The amino acid sequences are adjusted to promote the best folding and the most stable polypeptides and nucleic acid sequences are optimized to add restriction sites and to adjust for codon bias (column 44, lines 55-57).

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MKZ

MARY K. ZEMAN
PRIMARY EXAMINER
AU1631

November 13, 2002

Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow